K122338

510(k) Summary

807.92(c)

SPONSOR **807.92(a)(1)**

Company Name:	Prodigy Diabetes LLC
Company Address:	2701-A Hutchison McDonald Road Charlotte, NC 28269
Telephone:	704-285-6400
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Contact Person:	Rick Admani

NOV 05 2013

Summary Preparation Date: November 4, 2013

DEVICE NAME **807.92(a)(2)**

Trade Name:	Prodigy® Preferred Blood Glucose Monitoring System
Common/Usual Name:	Blood Glucose Meter
Classification Name:	System, Test, Blood Glucose, Over the Counter
Regulation Number:	862.1345
Product Code:	NBW, CGA
Device Class:	II
Panel:	Clinical Chemistry

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
Diagnostic Devices, Inc.	Prodigy Voice BGMS	K073118

DEVICE DESCRIPTION **807.92(a)(4)**

The Prodigy Preferred Blood Glucose Monitoring System consists of a meter and Prodigy No Coding Test Strips. The system utilizes an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions.

The Prodigy Preferred Blood Glucose Monitoring System is marketed as a meter only with a carrying case, battery, Owner's Manual, Quick Reference Guide, Logbook, and Warranty Card. The Prodigy Preferred Blood Glucose Monitoring System is also marketed as a meter kit with a carrying case, battery, Owner's Manual, Quick Reference Guide, Logbook, and Warranty Card,

Prodigy Lancing Device, Prodigy Lancets, Prodigy No Coding Test Strips, and Control Solution. The Prodigy No Coding Test Strips utilizes the active enzyme is Glucose Oxidase, derived from *Aspergillus niger.*

DEVICE INTENDED USE **807.92(a)(5)**

The Prodigy Preferred Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The Prodigy Preferred Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

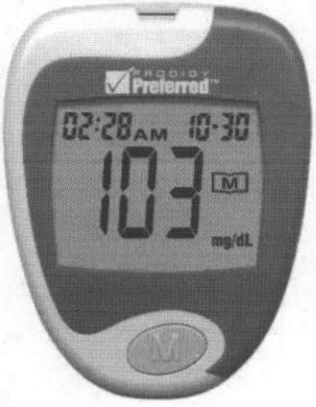
The Prodigy Preferred Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Prodigy Preferred Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Prodigy No Coding Test Strips are for use with the Prodigy Preferred Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh.

Predicate Product Comparison Chart

Item	Subject device	Predicate Device
Trade Name	Prodigy Preferred BGMS	Prodigy Voice BGMS
Manufacturer	Prodigy Diabetes Care, LLC	Diagnostic Devices, Inc.
K Number		K073118
Similarities		
Indications for Use	The Prodigy Preferred Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The Prodigy Preferred Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The Prodigy Preferred Blood Glucose Monitoring System is intended for self testing outside the body (in vitro	The Prodigy Voice Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus. The alternative site testing in this

	diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Prodigy Preferred Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly). The Prodigy No Coding Test Strips are for use with the Prodigy Preferred Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh.	system can be used only during steady-state blood glucose conditions.
Detection method	Amperometry: measuring a current produced by a chemical reaction	Amperometry: measuring a current produced by a chemical reaction
Enzyme	Glucose oxidase	Glucose oxidase
Test strip calibration	Code number checking	Code number checking
Temperature compensation	Automatic compensation with built-in thermister	Automatic compensation with built-in thermister
Sample volume (µL)	0.7 µL	0.7 µL
Reaction time (sec)	7	7
Measurement range	20-600 mg/dL	20-600 mg/dL
Operating condition	50° F – 104°F (10°C- 40°C), below 85% R.H. (noncondensing)	50° F – 104°F (10°C- 40°C), between 10% and 85% R.H. (noncondensing)
Strip vial opened use time	90 days	90 days
Auto shut off (min)	3	3
Alarm	Beeping sound and/or error message in LCD display	Beeping sound and/or error message in LCD display

Communication	RS232 port	RS232 port
Differences		
Memory feature	120 measurements with day and time	450 measurement with day and time
Day average	7-, 14-, 21-, 28- average glucose result	7-, 14-, 21-, 28-, 60- and 90 day average glucose result
Speaking function	no	yes
Weight	2.81 in. (L) x 2.375 in. (W) x 0.75 in. (H) 71mm (L) x 60mm (W) x 19mm (H)	3.78 in. (L) x 1.7 in. (W) x 0.71 in. (H) 95mm (L) x 55mm (W) x 18mm (H)
Dimension	1.6 oz with battery 45 g	2.4 ozs 68 g
Appearance	Picture / illustration of device 	Picture / illustration of device 

COMPARISON OF TECHNICAL CHARACTERISTICS **807.92(a)(6)**

Prodigy Preferred Blood Glucose Monitoring System has equivalent technological characteristics and intended use as the Prodigy Voice Blood Glucose Monitoring System (K073118). The Preferred Blood Glucose Monitoring System does not have the Voice capability.

PERFORMANCE TESTING **807.92(b)**

Precision test

According to the test results, the pooled and maximum SD were less than 5.0mg/dL at glucose concentration <75mg/dL, and pooled and maximum CV were less than 5.0% at glucose concentration ≥75mg/dL. The maximum individual bias was less than 10% compared with glucose analyzer YSI2300.The test results met the acceptance criteria.

Linearity

According to our test results, the correlation coefficient is greater than 0.95. That is, our test results and YSI 2300 were highly correlated. The linearity of our measurement is acceptable between 20 to 600 mg/dL. 100 % of the bias of individual glucose results fallen within ±10 %. The test results met the acceptance criteria.

System Accuracy

According to the test results, more than 95% test results of all alternative site tested fall within the acceptance criteria (15mg/dL for blood glucose level <75 mg/dL and 20% for blood glucose level ≧75mg/dL). The system accuracy of finger and AST of Prodigy Preferred Blood Glucose Monitoring System met the requirement of ISO 15197.

Interference

The Prodigy Preferred® Blood Glucose Monitoring System was tested for interfering substances. All the bias of test results were ˜ 10% compared with the measurements of the controlled pool. No obvious interference was observed in the interfering substance at therapeutic or physiological levels at three blood glucose levels. Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.

Elevated blood triglyceride, Reducing substances such as uric acid and ascorbic acid, Acetaminophen, Dopa, Methyldopa, L-dopa, and Tolbutamide (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.

Hematocrit

According to the data, when blood sample with HCT between 20% to 60%, all of the individual difference of the tests compared with individual YSI mean were less than ±10%. All of the individual bias of the tests compared with YSI mean in HCT 40% was less than ±10%. All SD were <5mg/dL and all CV were <5%. The test result supported an acceptance HCT range for Prodigy Preferred Blood Glucose Monitoring System was 20% to 60%.

Volume Verification Study

Based on the data, the sample volumes between 0.7to 1 .5µL were fall within acceptable criteria. In order to obtain more accurate results, testing blood glucose value with the Prodigy Preferred Blood Glucose Monitoring System required at least0.7µL of blood

Measurement Internal Determination Test

The glucose measurements with the check strip before and after high temperature exposure is less than 0.2 mg/dl. The mean difference of the before and after test strip measurements using the control solutions Level N and Level H is less than 3.6 mg/dl for each. The test results exceed the acceptance criteria of 2.0 mg/dL difference for the before and after exposure check strip measurements and 5.0 mg/dL mean difference for the before and after control solution measurements. The meters pass this performance test.

Altitude Study

It shows the individual results fall within ± 10 % at the altitude from 91 to 3,402 meters. The results meet the acceptance criteria. So it shows no significant effects on Prodigy Preferred Blood Glucose Monitoring System at various altitudes from 298 feet to 11,161 feet (91 to 3,402 meters).

Storage Condition for Prodigy No Coding Test Strips

According to the test results, all the individual bias was less than ± 10 %. The results show all the unused test strips were stable in a period of 24months and 90 days in used vials even after transportation.

Temperature for Equipment

The maximum individual bias of the meters treated to extreme temperature measurements compared with the YSI 2300 were <10% by using venous whole blood. The test results met the acceptance criteria.

Humidity test for Equipment

The maximum individual bias of the meters treated to extreme humidity measurements compared with the YSI 2300were <10% by using venous whole blood. The test results met the acceptance criteria.

Operating Condition for Prodigy No Coding Test Strips

According to the test results, the performance of individual bias of the test strips evaluated in the extreme environments was less than ± 10 %, the result meets the acceptance criteria.

Low Temperature Test

The glucose measurements with the check strip before and after low temperature exposure are less than 0.2 mg/dl. The mean difference of the before and after test strip measurements using the control solutions Level Normal and Level High are less than 3.9 mg/dl for each. The test results exceed the acceptance criteria of 2.0 mg/dL difference for the before and after exposure

check strip measurements and 5.0 mg/dL difference for the before and after control solution measurements. The meters pass this performance test.

Humidity Detection Limit

It shows that all CV of the test results are less than 4 %, that the data is accepted. The total CV of the average values at different humidity levels are less than 4 % for "Normal" and "High" control solution for the humidity range from RH 10 ~ 85%.

High Temperature Test

The glucose measurements with the check strip before and after high temperature exposure is less than 0.2 mg/dl. The mean difference of the before and after test strip measurements using the control solutions Level N and Level H is less than 3.6 mg/dl for each.

The test results exceed the acceptance criteria of 2.0 mg/dL difference for the before and after exposure check strip measurements and 5.0 mg/dL mean difference for the before and after control solution measurements. The meters pass this performance test.

Temperature Test

It shows that all precisions of the test results are less than 4 %, so that the data is accepted. The total CV of the average values at different temperatures are less than 4 % for "Normal" and "High" Prodigy control solution for the temperature range from 10 to 40°C.They are passed the temperature with the Operating temperature (10～40°C) and Storage temperature (4～40°C).
Robustness Test

According to the test results, the appearance, structure and function of the meters were quite regular after cleaning and disinfection cycles including 5,000 times for single-patient use claim, and the lancing devices were the same as the testing meters after 156 times cleaning and disinfection cycles. Also, based on the accuracy test, all the individual bias of the test results compared with YSI mean were less than 10 mg/dL at glucose concentrations < 75 mg/dL and less than ± 10 % at glucose concentrations ≧75 mg/dL. The test results met acceptance criteria.

Disinfection Efficacy Validation Study

In order to evaluate the efficacy of disinfection procedure with specified disinfectant that is DISPATCH®Hospital Cleaner Disinfection Towel with Bleach, coupons from the four test articles, Blood Glucose Meter were tested in this study. Our assay followed the guidance of FDA and carried out in a strict manner for safety considerations. The result revealed that HBV of clinical sera could be efficaciously removed from the Blood Glucose Meter provided by OKBiotech CO.,

Ltd after completing the designed disinfection procedure. The study demonstrates the disinfection procedure and virucidal would be a robust method to protect the users to avoid HBV infection.

Software Validation

The Software of Prodigy Preferred Blood Glucose Meter meets the requirements of FDA's guidance document "Guidance for the Content of Pre-market Submission for Software Contained in Medical Devices".

Human Factor Study

Ease of Use = 98.5%
Label Comprehension = 99.5%

Electrical Testing

EN 61236-1 EMC Test = Passed
EN 60601-1-2 EMC Test = Passed
FCC CFR 47 18 Subpart C = Passed
Design verification and validation testing confirmed that the performance, safety, and effectiveness of the Prodigy Preferred Blood Glucose Monitoring System was equivalent to that of the predicate device.

Conclusion

The Prodigy Preferred Blood Glucose monitoring System is substantially equivalent in its intended use, performance, safety, effectiveness and the underlying scientific and operating principles used, to the predicate Prodigy Voice Blood Glucose Monitoring System (K073118).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 5, 2013

PRODIGY DIABETES CARE, LLC
C/O E.J. SMITH, CONSULTANT
SMITH ASSOCIATES
1468 HARWELL AVENUE
CROFTON MD 21114

Re: K122338
Trade/Device Name: Preferred Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA
Dated: October 28, 2013
Received: October 29, 2013

Dear E.J. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K122338

Device Name
Prodigy Preferred Blood Glucose Monitoring System

Indications for Use *(Describe)*

The Prodigy Preferred Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh. The Prodigy Preferred Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

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The Prodigy No Coding Test Strips are for use with the Prodigy Preferred Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, calf or thigh.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stayce Beck